

# Use of Radiolabeled Platelets for Assessment of In Vivo Viability of Platelet Products

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May 3, 2004



# Historical approach to CBER evaluation of platelet products

- Center for Biologics Evaluation and Research (CBER) evaluates blood products for safety and efficacy
- Platelet efficacy has been evaluated, in part, by recovery and survival of radiolabelled platelets in healthy human volunteers
- Symposium on radiolabeling of stored platelet concentrates, Washington DC May 1984 (*Transfusion* 26 (1), 37-42, 1986)



# Current design of in vivo radiolabeled platelet studies

- Current approach compares performance of novel platelet product to a 5 day old licensed platelet product
- A small amount of decreased performance is acceptable due to variability in experimental results
- Licensing of the novel product sets a new standard which could be slightly lower than the previous standard
- Repeat applications of this process lead to decline of platelet product quality over time



# Alternate approach

- Establish a “gold standard” based on performance of fresh autologous platelets in a healthy donor
- Compare all future platelet products to fresh autologous platelets with a standardized protocol



# Future platelet products that may test the limits of platelet performance

- Pathogen reduced platelets
- Extended shelf life platelets
- Low temperature storage conditions
- Additive solutions for platelet storage
- New storage containers



# 2004 Workshop on Use of Radiolabeled Platelets for Assessment of In Vivo Viability of Platelet Products

- Review current evaluation practices for platelets
- Outline an alternate approach
- Present standardized study protocols
- Present preliminary data using the alternate approach
- Expert panel discussion on the appropriate standards using the alternate approach

# Workshop goal

- To orient the transfusion community towards a new approach for assessing the quality of platelet products through radiolabeling studies in healthy volunteers



# Workshop objectives

- Discuss merits of the novel approach to evaluating platelet products by radiolabeling studies
- Discuss appropriate study protocols for comparing platelet products to the standard.
- Reach consensus on establishing a minimum performance standard for platelet products in radiolabeling studies

